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09/011,940	03/03/1999	MICHAEL A. NAUCK	864861USWO	1535

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EXAMINER	
CELSA, BENNETT M	

ART UNIT	PAPER NUMBER
1639	39

DATE MAILED: 11/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

file copy

Office Action Summary	Application No.	Applicant(s)	
	09/011,940	NAUCK ET AL.	
	Examiner	Art Unit	
	Bennett Celsa	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period f r Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,17-19,21,23-25,32-35,41-46 and 48-55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *41-44,48,51 and 55* is/are allowed.

6)☒ Claim(s) *1,17-19,21,23-25,32-35,45,46,49-50 & 52-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Response to Amendment

Applicant's amendment dated 9/2/03 in paper no. 38 is acknowledged.

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

NOTE: applicant should review the status of the present claims to ensure accuracy with previous amendments of the present claims. For example, the claims (e.g. claim 46) were previously amended to insert "a nutritively effective amount" in response to outstanding prior art rejections. The present office action addresses the claims as presently portrayed by applicant including amended and newly presented claims which necessitate the raising of new ground(s) of rejections.

Status of the Claims

Claims 1, 17-19, 21, 23-25, 32-35, 41-46 and 48-55 are currently pending and under consideration.

Election/Restriction

Applicant's election with traverse of Group I (claims 1-2 and 17-25) and the species GLP-1 and glucose in Paper No. 12 is again acknowledged.

Withdrawn Objection (s) and/or Rejection (s)

Applicant's amendment has overcome the objection of claims 17-18 and 47 under 37 CFR 1.75(c), as being of improper dependent form

Applicant's amendment has overcome the rejection of claims 1, 17-19, 21, 23-26, 28-39, 41, 43-45 and 47-51 under 35 U.S.C. 112, second paragraph, as being indefinite

Applicant's arguments were found persuasive with respect to the new matter rejection of claim 42 in the prior office action.

New Objection (s) and/or Rejection (s)

Claim Rejections - 35 USC § 102/103

2. Claims 1, 17-19, 21, 23-25, 32, 35, 45 and 52-54 are rejected under 35 U.S.C. 102(b) as being anticipated by Baer et al. Diabetes Vol. 34 (Nov. 1985) pages 1108-112.

Baer et al. teach providing "non-alimentary nutrition" to a rat (e.g. "a patient in need of parenteral nutrition") by "parenterally" infusing (e.g. intravenously i.e. 1.6ug/kg in aqueus solution) a nutrient solution (e.g. comprising glucose and amino acids) and gastric inhibitory peptide (e.g. GIP which is an insulinotropic peptide). See entire article, especially abstract and page 1109, left column. The reference further teaches that mean plasma concentrations that provide plateau levels of GIP. E.g. see Figures; pages 1109-1110.

3. Claims 1, 17-19, 21, 23-25, 32, 35, 45 and 52-54 are rejected under 35 U.S.C. 102(b) as being anticipated by Amland et al. Scandinavian Journal of Gastroenterology, Vol. 20, No. 3 April 1985 pages 321-324.

Amland et al. teach (e.g. see page 321col. 2-page 322) providing "non-alimentary nutrition" to "fasting" humans (e.g. "a patient in need of parenteral nutrition") by "parenterally"

infusing (e.g. intravenously i.e. in aqueus solution) a nutrient solution (e.g. comprising glucose) and gastric inhibitory peptide (e.g. GIP which is an insulinotropic peptide). The reference further teaches that mean plasma concentrations that provide plateau levels of GIP. E.g. see page 322 under "Plasma GIP".

4. Claims 1, 17-19, 21, 23-25, 32-35, 45, 46 and 52-54 are rejected under 35 U.S.C. 102(e) as being anticipated by Habener, U.S. Pat. No 5,614,492 (3/97: filed 9/91 or earlier).

Habener "492 disclose the use of GLP 1 and its derivatives (e.g. col. 7) to treat both diabetes and hyperglycemia (e.g. see col. 6, lines 1-10) due to the peptide's "insulinotropic" activity (e.g. see col. 5, line 60-70). "Parenteral administration" of GLP 1 and its derivatives in pharmaceutical compositions comprising carbohydrates (e.g. lactose), polyamino acids: controlled release formulations comprising lipid derivatives (e.g. liposomes) e.g. see bottom of col. 9 to top of col. 10) as well as conjugates thereof (e.g. see col. 10, lines 13-26) anticipate the presently claimed invention. Further Example 11 (e.g. col. 21-28, especially "meal studies") disclose the administration of GLP-1 both during a meal (e..g 50% CHO; 30% fat; 20% protein: see e.g. col. 22, lines 55-67) and postprandial to both NORMAL and non-diabetic patients with the successful control of plasma glucose levels. See also patent claims 1 and 9 (and dependent claims thereon) teaching the use of GLP-1 and derivatives to treat diabetes and hyperglycemia.

Accordingly, the parenteral administration of GLP-1 and its derivatives before/during/after meals that both contained and generated CHO (e.g. especially glucose) anticipates the presently claimed invention. See also patent claims which additionally disclose the treatment of both diabetes and hyperglycemia utilizing GLP-1 containing compositions. The reference clearly incorporates the addition of compounds that are within the scope of the term "nutrients" (e.g. lactose, amino acids) both as separate compounds or as conjugates (e.g. see col. 9-10). Additionally, the patent reference further teaches administration of GLP compounds with a meal which presumably would contain nutrients (e.g. see col. 9-10 and examples).

5. Claims 1, 17-19, 21, 23-25, 32-35, 45, 46, 49-50 and 52-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Specification disclosure as to the state of the prior art in view of Habener, U.S. Pat. No. 5,614,492 (3/97: filed 9/91 or earlier) and/or Eng US Pat. No. 5,424,286 (6/95) .

The specification on pages 1-2 and page 10, lines 15 describes the state of the prior art regarding the necessity for providing parenteral nutrition to patients having "disturbed glucose metabolism" (e.g. surgery patients, shock etc) as well as to malnourished patients while overcoming the hyperglycemia that accompanies parenteral nutrition. Coadministration of insulin with parenteral nutrition in order to overcome the hyperglycemia problem has its drawbacks (e.g. see page 1, lines 13-25).

The State of the Prior Art as described in the specification differs from the presently claimed invention which incorporates the use of "insulinotropic peptides" (e.g. GLP-1 and its

derivatives) in parenteral nutrition compositions which comprise nutrients (e.g. glucose or glucose generating compounds) for alimentary nutrition or to treat hyperglycemic states.

However, both the Habener and Eng Patent references teach the "insulinotropic" nature of GLP-1 and related peptides e.g. the ability of these peptides to endogenously generate insulin and thus combat hyperglycemia.

Additionally, the prior/sequential and co-administration of these "insulinotropic" peptides with a meal containing nutrients (e.g. which include glucose or generate glucose) and the peptides concomitant ability to obtain normalized glucose levels is both disclosed and suggested by the Habener and/or Eng patents (e.g. see Habener, Example 11, col. 21-28 and patent claims addressing treatment of diabetes and hyperglycemia; e.g. see Eng at col. 1, lines 49-67 disclosing lowering of meal-related glucose levels by parenteral administration of GLP-1 and GLIP which effect was also found with other "insulinotropic" peptides (e.g. exendins) alone or in combination (including sequential) with GLP-1 (e.g. see Eng col. 2, lines 35-40; col. 5, lines 14-20; Example 2 (col. 6-7); Example 5 relating to diabetics; and patent claims 5-6.

The determination of optimal amounts of "insulinotropic" peptides and/or nutrients taken sequentially or in combination is well within the skill of the art as well as the determination of optimal delivery formulations (e.g. tablets, pills, delayed release etc.) and time of delivery (e.g. coadministered, sequential etc.).

One of ordinary skill in the art would be motivated to substitute the "insulinotropic" peptides disclosed by the Eng or Habener references for insulin in "parenteral" formulations as

disclosed in the Specification, due to the problematic use of insulin as discussed in the specification and in view of the ability of "insulinotropic peptides" to endogenously produce insulin as taught by the Eng and/or Habener references.

Accordingly, the incorporation of "insulinotropic" peptides (e.g. GLP-1 or its derivatives) into parenteral formulations containing "nutrients" to treat diabetics, non-diabetics (e.g. hyperglycemia) or malnourished individuals would have been obvious to one of ordinary skill in the art at the time of applicant's invention in view of the Habener and/or Eng references which demonstrate that administration of these peptides to obtain normalized glucose levels; regardless of the cause of hyperglycemia (meal/diabetes/hyperglycemia etc.).

Allowable Subject Matter

6. Claims 41-44, 48, 51 and 55 are allowable over the prior art of record.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR

1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

General information regarding further correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Celsa whose telephone number is (703) 305-7556.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang (art unit 1639), can be reached at (703)306-3217.

Any inquiry of a general nature, or relating to the status of this application, should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Bennett Celsa (art unit 1639)

November 7, 2003

BENNETT CELSA
PRIMARY EXAMINER